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EXAMINER

NAFF, D

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1651

32

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

08/928893

Applicant(s)

Heikkila et al

Examiner

Haff

Group Art Unit

1651

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 9/12/97
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1, 3-13, 15, 16 + 19-22 is/are pending in the application.
- ☐ Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1, 3-13, 15, 16 + 19-22 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☒ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).
- *Certified copies not received: _____.

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 31 (filed 5/7/01) ☐ Interview Summary, PTO-413
- ☒ Notice of Reference(s) Cited, PTO-892 ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948 ☐ Other _____

Office Action Summary

This application is a file wrapper continuation (FWC) of application 07/910,133.

The preliminary amendment of 7/12/99 has been entered. The amendment amended the specification and claims 1, 3, 4, 11, 19 and 20, and added claims 21 and 22.

Claims examined on the merits are 1, 3-13, 15, 16 and 19-22 which are all claims in the application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-13, 15, 16 and 19-22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification fails to contain adequate support for "lignocellulose-based, hexose-rich material" in line 2 of claim 1 and where recited in other claims, and for "wherein a majority of starting material is processed" in the last line of claim 1.

The portions of the specification referred to in the preliminary amendment as providing support do not recite "lignocellulose-based,

hexose-rich material", and there is not sufficient support for this recitation. While working examples disclose percentages of glucose (hexose) produced, this is not adequate support for the broader language "hexose-enriched" that encompasses any hexose and any amount that might
5 be considered enriched. While the specification recites "lignocellulose-containing material" (page 1, line 6) this does not support "lignocellulose-based" which can have a different meaning.

The specification fails to recite "wherein a majority of starting material is processed". While the specification recites "substantially
10 the entire starting material is utilized" (page 4, bridging lines 22 and 23), this is regard to utilization of the hydrolyzed lignocellulose-containing material as a starting material by fermenting the material with yeast to produce xylitol and ethanol (page 1, lines 6-7, and page 3, line 34). This disclosure fails to support the claimed recitation which
15 does not specify the starting material, and relates to starting material processed rather than starting material utilized.

The specification further fails to support hydrolysis in claim 22 as required by claim 11. The specification does not describe how hydrolysis is carried out in the alternative embodiment of claim 22 described at
20 page 9, lines 4-13. There is no description that one or both steps of hydrolysis in claim 22 can be performed as required by claim 11.

Claims 11 and 22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains,
25 or with which it is most nearly connected, to make and/or use the invention.

The specification fails to provide an enabling description of how to perform the embodiment of claims 11 and 22. The only description of this embodiment in the specification is at page 9, lines 4-13. No working example or other description is provided. It would be uncertain as to
5 conditions and materials including any enzymes and/or microorganisms required for partial hydrolysis, extracting, fermenting to produce xylitol, final hydrolysis and fermenting to produce ethanol. The steps in this process are sufficiently different from the steps used in claim 1 that it does not appear steps and conditions used in the claim 1 as
10 described in the specification will also apply to the process of claim 22. For example, claim 22 requires extracting the lignocellulose-based, hexose-rich material. Is this material the hydrolyzed lignocellulose-based, hexose-rich material of claim 1 and is hydrolysis carried out in the same way as described in the specification for producing the
15 hydrolyzed material of claim 1? The specification (page 9, lines 5-6) requires subjecting the starting material to partial hydrolysis. How do conditions and steps for this partial hydrolysis differ from conditions and steps described in the specification for producing the hydrolyzed material used as starting material in claim 1? How is extracting
20 performed, i.e. is extracting carried out by filtering the partial hydrolyzate or is extracting performed in some other way? Is fermenting the extract carried out with the same yeast and using the same conditions as described in the specification when producing xylitol by fermenting a hydrolyzed lignocellulose-containing material or is fermenting the
25 extract performed some other way? Is fermenting the extracted mass (bridging lines 4 and 5 of claim 22) performed the same way using the

same conditions as when previously fermenting the extract, and is this the same method described in the specification for fermenting the hydrolyzed lignocellulose-containing material? How is hydrolyzing in line 4 of claim 22 carried out? Is this hydrolyzing performed in the same way as described in the specification for hydrolyzing a lignocellulose-containing material and is this hydrolyzing performed using the same steps and conditions used to initially hydrolyze the lignocellulose-containing material? There is no description in the specification of carrying out one or both hydrolysis steps in claim 22 as required by claim 11.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-13, 15, 16 and 19-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In line 2 of claim 1 and where recited in other claims, "lignocellulose-based, hexose-rich" is uncertain as to meaning and scope. Being lignocellulose-based and hexose-rich is relative and subjective and depends on individual definition. The specification fails to recite and define "lignocellulose-based" and "hexose-rich". Additionally, hexose-rich is unclear as to whether being hexose-rich is before or after hydrolysis. The specification discloses hexose being present only after

hydrolysis, and the claim should be made consistent with the specification.

In the last line of claim 1, "wherein a majority of starting material is processed" is uncertain as to meaning and scope. The claim
5 fails to contain clear antecedent basis for "starting material" and "processed", and the claim is unclear as to material that is the starting material and the process that constitutes the starting material being processed.

Claim 3 is confusing and unclear by requiring the lignocellulose-
10 based, hexose-rich material to be birch or grain hulls since the birch and grain hulls do not contain hexose which is produced by hydrolyzing the birch and grain hulls.

Claim 4 is confusing and unclear by requiring a sulphite spent liquor to be lignocellulose-based since Table 2 on page 14 of the
15 specification does not show lignocellulose being present in sulphite spent liquor before fermentation. Additionally, Example 2 (page 13) and Table 2 show fermenting sulphite spent liquor without prior hydrolysis. It appears the spent liquor is not used in a process as required by claim 1 since the liquor already contains glucose and xylose without
20 hydrolysis, and the liquor does not contain lignocellulose.

Claim 11 is unclear as to which hydrolysis step in claim 22 is being further limited.

In line 2 of claim 21, "posthydrolysis" is confusing and unclear. What is the hydrolysis "post" to. Does this mean that hydrolysis is
25 after steam explosion or after some other step? If "post" means hydrolysis is after steam explosion, the claim should recite "steam

explosion followed by hydrolysis". If hydrolysis is after some other step, the step should be recited, and "followed by hydrolysis" recited thereafter.

Claim 22 is confusing and unclear how the steps of claim are carried
5 out together with the steps of claim 1. In view of the specification
(page 9, lines 4-5), the process of claim 22 is a complete process that
is alternative to the process of claim 1. In this case, claim 22 should
be in independent form since the process of claim 22 replaces the entire
process of claim 1 with steps different than performed in claim 1 such
10 that the process of claim 1 no longer exists. A dependent claim properly
dependent on claim 1 should further limit the process of claim 1 rather
than replace the process of claim 1 with a completely different process
that precludes the process steps of claim 1.

Bridging lines 3 and 4 of claim 22, "crystallizing the xylitol
15 solution" is unclear since xylitol rather than the solution is
crystallized.

Claims 1, 3-10, 12, 13, 15, 16, 19, 20 and 21 are rejected under 35
U.S.C. 102(b) as being anticipated by Heikkila et al (5,081,026).

The claims are drawn to the simultaneous production of xylitol and
20 ethanol by fermenting a hydrolyzed lignocellulose-based, hexose-rich
material with yeast to form a fermented product containing xylitol,
ethanol and yeast, recovering ethanol, chromatographically separating a
xylitol-rich fraction and recovering xylitol from the xylitol-rich
fraction. A majority of starting material is processed.

25 Heikkila et al disclose (paragraph bridging cols 2 and 3) fermenting
a hydrolyzed lignocellulose-containing material to produce a hydrolyzate

containing xylose and hexoses, fermenting the hydrolyzate with yeast to produce a fermented product containing xylitol, ethanol and yeast, removing yeast, removing ethanol by evaporation or distillation, chromatographically separating a xylitol-rich fraction and recovering
5 xylitol from the xylitol-rich fraction.

The present claims encompass the process of Heikkila et al. The amount of hexose required by the term "hexose-rich" in the claims is relative and subjective, and does not require a greater amount of hexose than contained in the hydrolyzed lignocellulose-containing material of
10 Heikkila et al. Additionally, the claims requiring a majority of starting material to be processed does not require processing a greater amount of starting material than in the process of Heikkila et al. The term "majority" requires the amount of starting material processed to be only greater than 50%. The amount of starting material processed in the
15 process of Heikkila et al appears to be greater than 50% since there seen nothing in the process that will result in 50% or less of the starting material not being processed.

Applicant's arguments filed 7/12/99 have been fully considered but they are not persuasive.

20 Applicants state in the amendment that the claims have been amended to specify a lignocellulose-based, hexose-rich material and that a majority of starting material is processed. Applicants' amendment and a
37 C.F.R. § 1.132 Declaration by Heikkila point out that in Heikkila et al a majority of the raw material is lost due to a high amount of xylose
25 and low amount of glucose being produced by mild hydrolysis to obtain a high yield of xylitol and low amount of ethanol. The amendment and

declaration urge that the present invention uses a more severe hydrolysis to produce a high amount of both hexose and xylose resulting in a high yield of both ethanol and xylitol as a usable products and a lower amount of waste.

5 This argument is unpersuasive since the terms "hexose-rich" and "majority of starting material" used in the claims to distinguish from Heikkila et al are sufficiently imprecise, functional and broad as not to require a different amount of hexose and starting material processed than in the process of Heikkila et al. The amount of hexose obtained in the
10 process of Heikkila et al can be considered "rich" as compared to a lower amount, and there is inadequate evidence to establish that 50% or less of the starting material in not processed in the process of Heikkila et al. Removing ethanol by distillation as taught by Heikkila et al results in recovery of the ethanol, and Heikkila et al nowhere disclose discarding
15 ethanol removed by distillation. Moreover, if Heikkila et al does not intend to recover the ethanol, there is no reason to remove the ethanol since the xylitol can be recovered without removing the ethanol.

Claims 1, 3-13, 15, 16 and 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heikkila et al in view of Chahal (5,047,332).

20 The invention and Heikkila et al are described above.

Chahal discloses (col 5, lines 20-29) producing ethanol for use as fuel from lignocellulose-containing biomass by fractionating lignocellulose into cellulose, lignin and hemicelluloses, hydrolyzing the cellulose with cellulase to produce glucose and fermenting the glucose
25 with yeast to produce ethanol.

It would have been obvious to increase the amount of ethanol produced in the process of Heikkila et al to provide ethanol for use as fuel as suggested by Chahal by hydrolyzing cellulose of lignocellulose to glucose so that yeast can ferment the glucose to ethanol. The xylose
5 obtained by Heikkila et al results from hemicellulose (col 1, lines 55-61). It would have been apparent from Chahal that lignocellulose material contains cellulose in addition to hemicellulose, and the cellulose can be hydrolyzed with cellulase to glucose for fermenting to ethanol. Thus, it would have been expected that cellulose in addition to
10 hemicellulose is present in the lignocellulose material used by Heikkila et al (col 3, lines 51-68) as a starting material, and it would have been obvious to hydrolyze the cellulose to glucose to provide increased production of ethanol for fuel use as suggested by Chahal. Producing xylitol and ethanol in separate steps as in claim 22 would have been a
15 matter of obvious choice depending on individual preference and convenience within the ordinary skill of the art.

Arguments in the amendment and declaration in regard to Heikkila et al are unpersuasive since in view of Chahal it would have been obvious to increase the production of ethanol in the process of Heikkila et al to
20 obtain ethanol for use as fuel. Chahal clearly suggest how increased ethanol production can be accomplished by hydrolyzing cellulose of lignocellulose material with cellulase to produce glucose that can be fermented to ethanol.

Claims 1, 3-13, 15, 16 and 19-22 are rejected under the judicially
25 created doctrine of obviousness-type double patenting as being

unpatentable over claims 1-28 of U.S. Patent No. 5,081,026 in view of Chahal for reasons set forth above in the 35 U. S. C. 103 rejection.

It would have been obvious to increase the amount of ethanol produced in the claimed process of the patent to obtain ethanol for fuel use as suggested by Chahal by hydrolyzing cellulose in the starting material with cellulase to obtain glucose that can be fermented to ethanol.

On form PTO-1449, publication dates have not been provided for the following documents: Dorfner, Zaborsky, Sax, Morrison, International Preliminary Examination Report (PCT/FI91/00011), Official Action (FI 900220), International Search Report (PCT/FI90/00015), and Horitsu. A publication date should be provided for each document. Any document not provided with a publication date will be deleted from the form and not be made of record on a patent that may issue. Additionally, it is unclear why document FI 900220 is listed on the same line together with document PCT/FI91/00011. These appear to be two separate documents, and each should be listed on a separate line with a date the document became available to the public. Also, is FI 900220 a PCT? If any of the documents missing a publication date has not been published and become available to the public, applicants should state that the document has not been published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is (703) 308-0520. The examiner can normally be reached on Monday-Thursday and every other Friday from about 8:30 AM to about 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, a message can be left on voice mail.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn, can be reached at telephone number
5 (703) 308-4743.

The fax phone number is (703) 305-3014 or 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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15 DMN
5/10/01


DAVID M. NAFF
PRIMARY EXAMINER
ART UNIT 1651